REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS & AMENDMENTS

Claims 2-14, 17, 19-33, 35-40 and 42 were pending in this application when last examined, and stand rejected.

Claims 2, 17, 22 and 23 have been amended to remove the phrase "or a compound including the same." Support for this change can be found in the claims as originally filed. It is respectfully submitted that such amendment does not affect the scope of the claims. In this regard, the claims are in "comprising" format, and thus, cover compounds including/containing lauric diethanolamide.

Claim 17 has been amended to include the elements of original claim 4.

Therefore, no new matter has been added by this amendment.

Claim 4 has been cancelled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any cancelled subject matter.

Upon entry of this amendment, claims 2, 3, 5-14, 17, 19-33, 35-40 and 42 will be pending.

II. FINALITY

Kindly reconsider the finality of the previous Office Action.

On page 5 of the Office Action dated February 26, 2004, it was indicated that the prior art fails to disclose or suggest the elected composition comprising (S)-N-[2-(1,6,7,8-tetrahydro-2H-indeno[5 ,4-b]furan-8yl)ethyl]propionamide plus lauric diethanolamide. It is noted that the previous claim set, specifically, dependent claim 6 was drawn to this embodiment. Moreover, the subsequent amendment filed September 3, 2004 did not alter the scope of the claims (i.e., did not add any new embodiments). Thus, the newly cited references were not necessitated by the prior amendment.

In view of the above, please reconsider and/or clarify the finality of the Action.

III. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 2-14, 17, 19-33, 35-40 and 42 were rejected under 35 U.S.C. § 112, second paragraph, on the basis that the phrase "or a compound including the same" is indefinite. See page 2 of the Office Action.

It is respectfully submitted that the present amendment, which deletes this language, overcomes this rejection.

IV. REJECTIONS UNDER 35 U.S.C. § 103(a)

A. Claims 2-6, 8-14, 17, 19, 22-32 and 35-38

Claims 2-6, 8-14, 17, 19, 22-32 and 35-38 were rejected under 35 U.S.C. § 103(a) as obvious over Ohkawa et al., WO 99/63977, Carelli et al., Int. J. of Pharmaceutics, Vol. 88 (1-3), pp. 89-97 (Abstract), Nelson et al., WO 89/07951 and Corbiere, WO 85/04106. See pages 2-3 of the Office Action.

This rejection is respectfully traversed as applied to the amended claims for the following reasons.

To establish obviousness, there must be some suggestion or motivation in the references to either modify or combine the reference teachings to arrive at the claimed invention. M.P.E.P. § 2143.01.

In this case, the cited references lack a suggestion to combine the compound disclosed in Ohkawa with the ingredients in the other references to arrive at the claimed invention.

The Action indicates that one having ordinary skill in the art would have been expected to make a single composition comprising all of the claimed ingredients since all individual teachings are to treatment of sleep order. See page 3, lines 11-13 of the Office Action. However, the ingredients disclosed in the references, other than Ohkawa, are mere additives for pharmaceutical compositions for different active components. Even if a disease to be treated is the same, whether

an additive used for one active component can be used for another different active component cannot be predicted. Instead, the additives should be selected based on physicochemical properties and biochemical properties of the active component, rather than the disease to be treated.

The active component of the present invention has been limited to that previously claimed in claim 4 (now cancelled) and now added to independent claim 17. Ohkawa discloses a composition for treating a sleep disorder comprising (S)-N-[2-(1,6,7,8-tetrahydro-2H-indeno[5 ,4-b]furan-8yl)ethyl]propionamide (hereinafter referred to as Compound A). However, the cited references, other than Ohkawa, are irrelevant as to this active compound. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. M.P.E.P. § 2143.01. Accordingly, there is no motivation to combine the compound disclosed in Ohkawa with the additive ingredients of the other references.

Furthermore, Ohkawa is drawn to a composition comprising a combination of Compound A and another active component. There is no teaching or suggestion of a percutaneous absorption preparation of Compound A by itself in Ohkawa.

The Action indicates that Carelli discloses a composition for treating depression (sleep disorder) comprising lauric acid diethanolamide. However, Carelli is drawn to a skin-permeation test of Alprazolam, which is an antidepressant, and merely indicates that lauric acid diethanolamide is an additive for enhancing skin permeation of Alprazolam. Carelli mentions nothing about the treatment of a sleep disorder with Compound A. Carelli does not disclose or suggest that lauric acid diethanolamide is an additive capable of enhancing skin permeation of Compound A. As such, Carelli is irrelevant to treatment of a sleep disorder with Compound A.

Nelson is drawn to a pressure-sensitive adhesive sheet material for delivering estradiol. Isopropyl myristate, which, as pointed out by the Examiner, is an additive for enhancing skin-penetration of estradiol. However, Nelson, like Carelli, mentions nothing about a treatment of sleep disorder with Compound A. Nelson is simply irrelevant to the claimed invention for the treatment of sleep disorder with Compound A.

Corbiere is drawn to stabilization of a pharmaceutical active agent in an aqueous phase. However, as seen from the description, at page 72, lines 6 to 10 of the instant specification, all of the ingredients are dissolved in a volatile organic solvent. Accordingly, an aqueous phase is not used in the present invention. Thus, Corbiere's stabilization in an aqueous phase is irrelevant to the present invention.

In fact, Corbiere's stabilization in an aqueous phase teaches away from the present invention. It is well established that the prior art must be considered in its entirety and that references cannot be combined where the references teach away from their combination. See M.P.E.P. § 2145 X, D, 2. A reference can be said to teach away when a person of ordinary skill in the art, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path taken by the applicant. In this case, upon Corbiere, the skilled artisan would be led in a path different from the present invention.

In view of the above, there is no motivation to combine Ohkawa with the other references to arrive at the claimed invention. Instead, the rejection appears to employ impermissible hindsight based on the Applicant's disclosure.

Thus, the rejection of claims 2-6, 8-14, 17, 19, 22-32 and 35-38 under 35 U.S.C. § 103(a) over Ohkawa, Carelli, Nelson and Corbiere is untenable and should be withdrawn.

B. Claims 2, 3, 8-14, 17, 35-40 and 42

Claims 2, 3, 8-14, 17, 35-40 and 42 were rejected under 35 U.S.C. § 103(a) as obvious over Ebadi et al., J. of Pineal Res., Vol. 24 (4), pp. 193-200 (1998) and Sekine et al., EP 879 597. See pages 3-4 of the Office Action.

It is respectfully submitted that the present amendment overcomes this rejection as applied to the amended claims for the following reasons.

To establish obviousness, the prior art references must teach or suggest each and every element of the claimed invention. M.P.E.P. § 2143.03. Also, there must be some suggestion or

motivation in the references to either modify or combine the reference teachings to arrive at the claimed invention. M.P.E.P. § 2143.01.

In this case, the cited references fail to disclose or suggest the claimed percutaneous absorption preparation comprising a melatonin receptor agonist using Compound A as the active component and lauric diethanolamide. The cited references also lack the requisite motivation to combine their teachings.

Instead, the Action indicates that one of ordinary skill in the art would have been motivated to make the claimed composition to develop an optimum treatment for pain and that one would have been motivated to do this since both prior art references individually teach pain treatment regimens. See page 4, lines 2-5 of the Office Action. However, this position is improper, because the cited references fail to disclose the active component (Compound A) of the amended claims.

As discussed above, the active component of the present invention has been limited to that previously claimed in claim 4 (now cancelled) and now added to independent claim 17. It is noted that claim 4 was not included in the instant rejection.

Ebadi, which relates to melatonin, is irrelevant to the amended claimed invention. Ebadi simply does not teach or suggest a percutaneous absorption preparation of the claimed compounds.

Sekine is drawn to stabilization of diclofenac sodium in water, and thus, is also irrelevant to the present invention, because, as discussed above, no aqueous phase is used in the present invention.

There is no motivation to combine Ebadi with Sekine.

Furthermore, notwithstanding that the claimed invention is not obvious over the cited prior references, the data from Test Example 1 on page 88, line 15 to page 90, line 16 of the specification clearly shows that the instant invention possesses unexpected advantages. For instance, in claim 2 of the present invention, both a water soluble absorption promoting agent, i.e., polyhydric alcohol, and lipid soluble absorption promoting agent, i.e., fatty acid ester, are used to realize one peak of blood-drug-concentration-time profile that reaches the maximum blood concentration 6 to 8 hours after affixing. See Test Example 1. This result is due to the physicochemical properties of the claimed active compound (Compound A). See page 54 of the specification. The cited references

fail to teach or disclose a compound containing this unexpected advantage of the present invention. Such an unexpected advantage is indicative of the non-obviousness of the present invention.

Thus, the rejection of claims 2, 3, 8-14, 17, 35-40 and 42 under 35 U.S.C. § 103(a) over Ebadi and Sekine is untenable and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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